REMARKS

Claims 1-9, 14, 17 and 22 are all the claims pending in the application.

Claim Rejections under 35 U.S.C. § 103

Referring to page 4 of the Action, claims 1-9, 14, 17 and 22 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent No. 6,660,300 (Timmins).

Applicants traverse and respectfully request the Examiner to reconsider in view of the following remarks.

The present invention relates to a pharmaceutical preparation exhibiting gastrointestinal absorbability comprising a mixture of (a) a compound recognized by a proton-coupled transporter, and (b) a pH-sensitive polymer. The pH-sensitive polymer is present in an amount sufficient to impart to the gastrointestinal tract a pH at which the proton-coupled transporter optimally functions for cellular uptake of the compound. The pH-sensitive polymer is at least one member selected from the group consisting of dried methacrylic acid copolymer, methacrylic acid copolymer LD, methacrylic acid copolymer L, methacrylic acid copolymer S, polyacrylic acid, maleic acid/n-alkyl vinyl ether copolymer, hydroxpropylmethylcellulose acetate succinate, and hydroxypropylmethylcellulose phthalate. The amount of the pH-sensitive polymer is 5 to 40 wt % based on the weight of the entire pharmaceutical preparation.

Timmins discloses a biphasic controlled release delivery system for pharmaceuticals which have a high water solubility. The delivery system includes: (1) an inner solid particulate phase formed of substantially uniform granules containing a pharmaceutical having a high water solubility, and one or more hydrophilic polymers, one or more hydrophobic polymers and/or one or more hydrophobic material; and (2) an outer solid continuous phase containing the above granules of inner solid particulate phase which are embedded and dispersed throughout, and one

or more hydrophobic polymers, one or more hydrophobic polymers and/or one or more hydrophobic material (Abstract).

Timmins fails to disclose a proton-coupled transporter and a pH-sensitive polymer as recited in claim 1.

Timmins exemplifies Eudragit as a hydrophobic polymer; however, this does not meet the requirement of a pH-sensitive polymer as recited in the presently claimed invention. In like manner, Timmins fails to disclose that the amount of the pH-sensitive polymer is 5 to 40 wt % based on the weight of the entire pharmaceutical preparation.

With regard to the latter deficiency, the Examiner states at page 4 of the Action, "Both the inner and outer phases are expressly taught as comprising hydrophobic polymers preferably ranging from 35-60% by weight of the entire composition (col. 10, lines 24-34)." However, this is inaccurate. At col. 10, lines 24-34, Timmins discloses that the total polymer (one or more hydrophilic polymers, one or more hydrophobic polymers and/or one or more hydrophobic material present in the inner phase; and one or more hydrophobic polymers, one or more hydrophobic polymers and/or one or more hydrophobic material in the outer solid phase) is 35-60%. The Examiner also states, "Regarding the limitations of claim 22 wherein said range is narrowed to 10-20 wt % of the entire composition, the invention of Timmins also expressly teaches that the inner phase may comprise from about 15 to about 95% by weight in the form of hydrophobic polymers (col. 9, lines 59-67). This is also inaccurate. At col. 9, lines 59-67, Timmins discloses that the inner phase will contain [the] drug in an amount preferably from about 15 to about 95% by weight.

Accordingly, Timmins fails to discloses or suggests both a proton-coupled transporter and a pH-sensitive polymer present in an amount sufficient to impart to the gastrointestinal tract

a pH at which the proton-coupled transporter optimally functions for cellular uptake of the compound as recited in the presently claimed invention.

Timmins does not disclose or suggest each and every element of the presently claimed invention, and a person having ordinary skill in the art would not arrive at the claimed invention based on the disclosure of Timmins. Therefore, the present invention is patentable over Timmins.

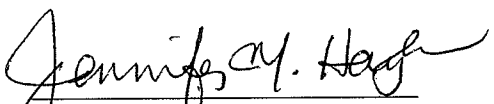
In view of the above, withdrawal of the § 103(a) rejection of claims 1-9, 14, 17 and 22 based on Timmins is respectfully requested.

Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,



Jennifer M. Hayes
Registration No. 40,641

SUGHRUE MION, PLLC
Telephone: (202) 293-7060
Facsimile: (202) 293-7860

WASHINGTON OFFICE
23373
CUSTOMER NUMBER

Date: January 19, 2010